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(54) **CATHETER WITH DIRECTED FLOW DESIGN**

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(52) **U.S. Cl.**
USPC **604/523**

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See application file for complete search history.

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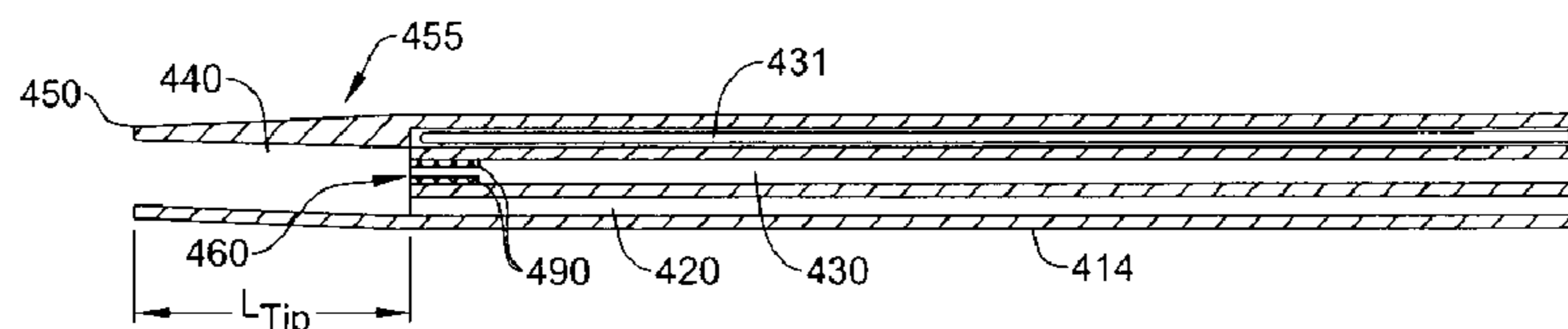
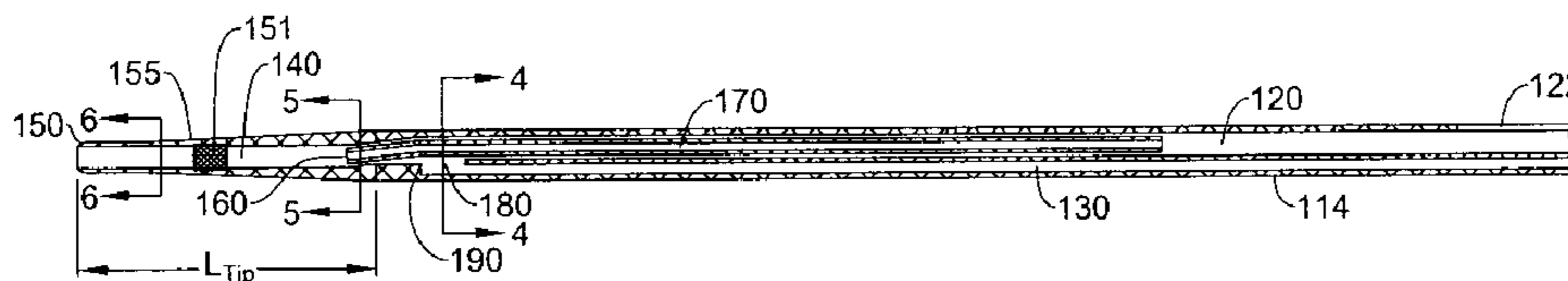
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(57) **ABSTRACT**

A catheter includes an elongated catheter body having a proximal portion and a distal portion. A first longitudinally accessible lumen and a second lumen extend side by side within and along the proximal portion, and the first lumen and the second lumen form a single common lumen within the distal portion which extends to a distal end of the distal portion. The first lumen and second lumen are co-axial within the distal portion prior to forming a single common lumen.

18 Claims, 3 Drawing Sheets



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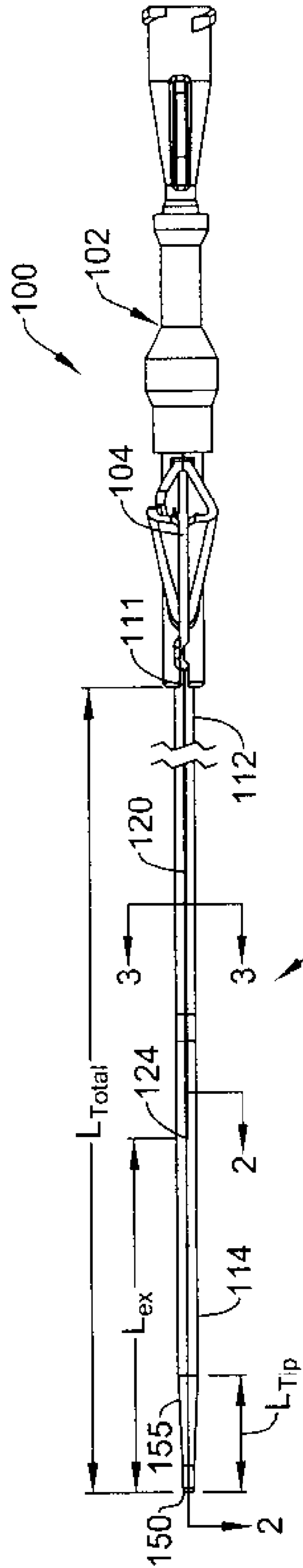


Figure 1

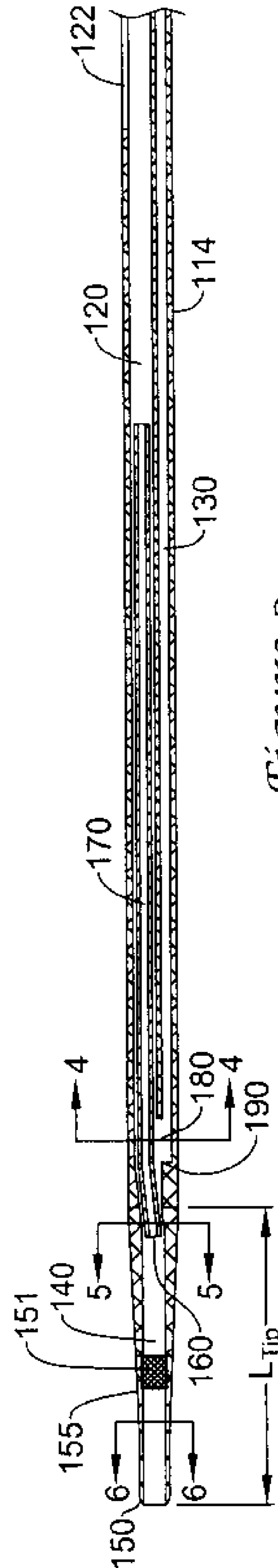


Figure 2

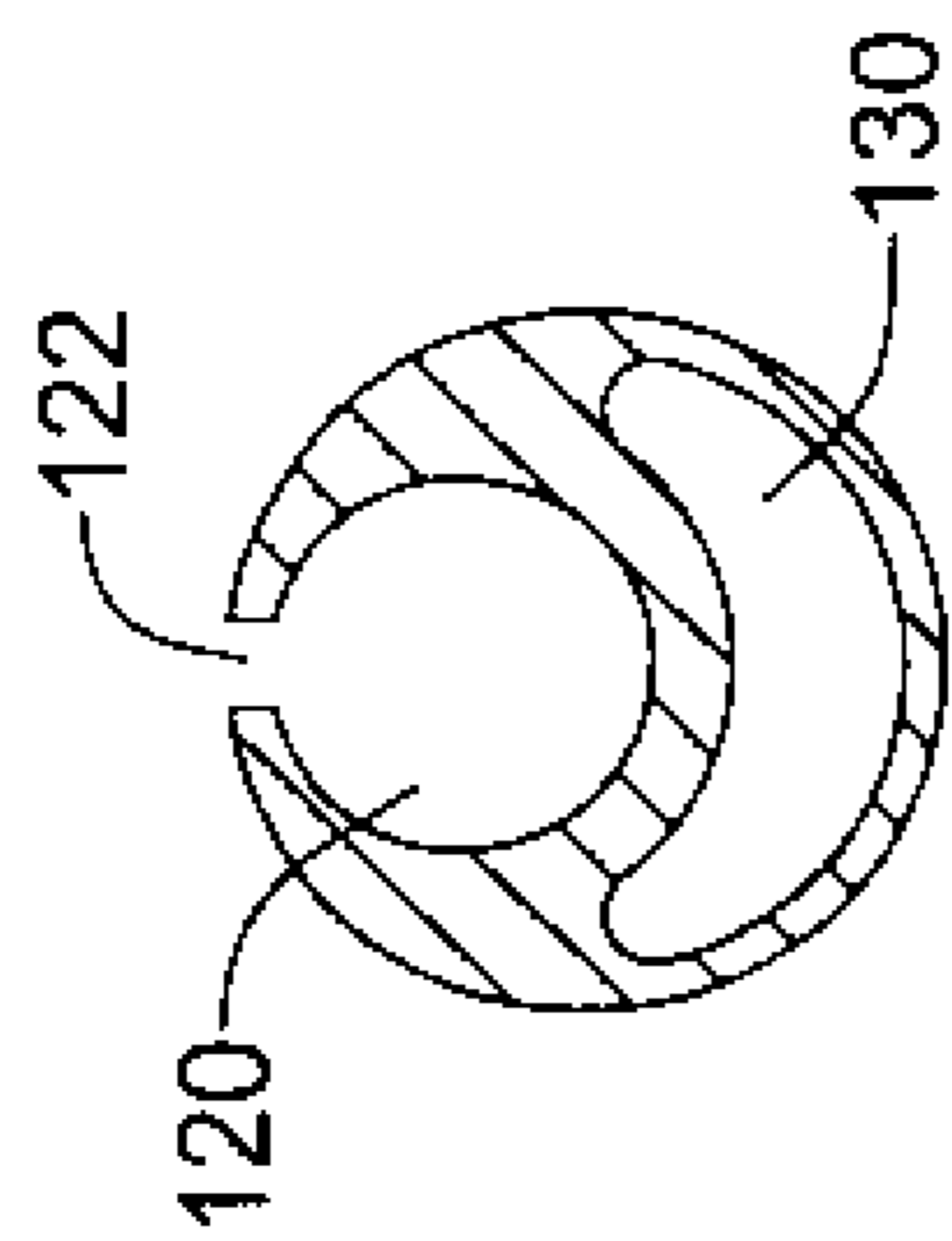


Figure 3

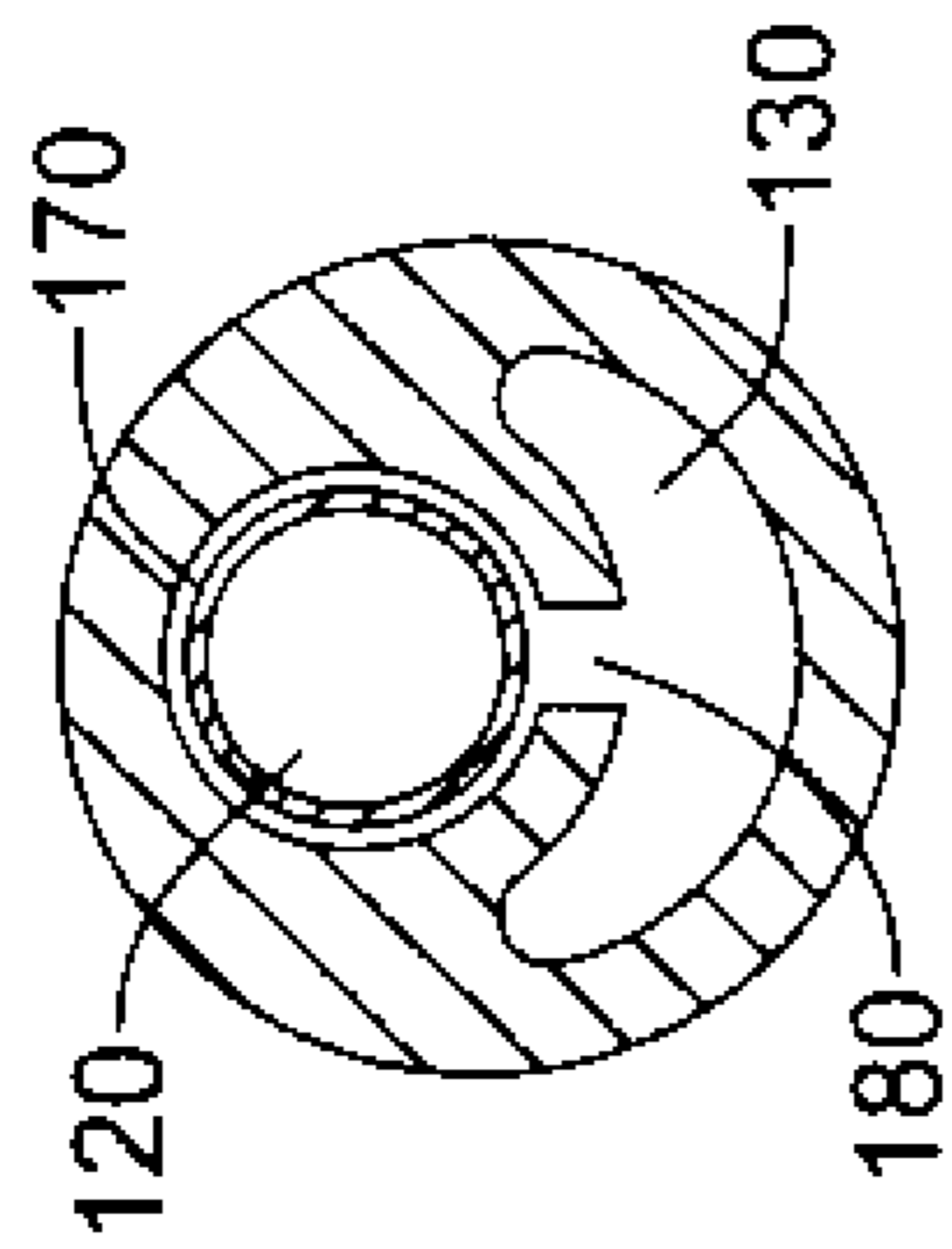


Figure 4

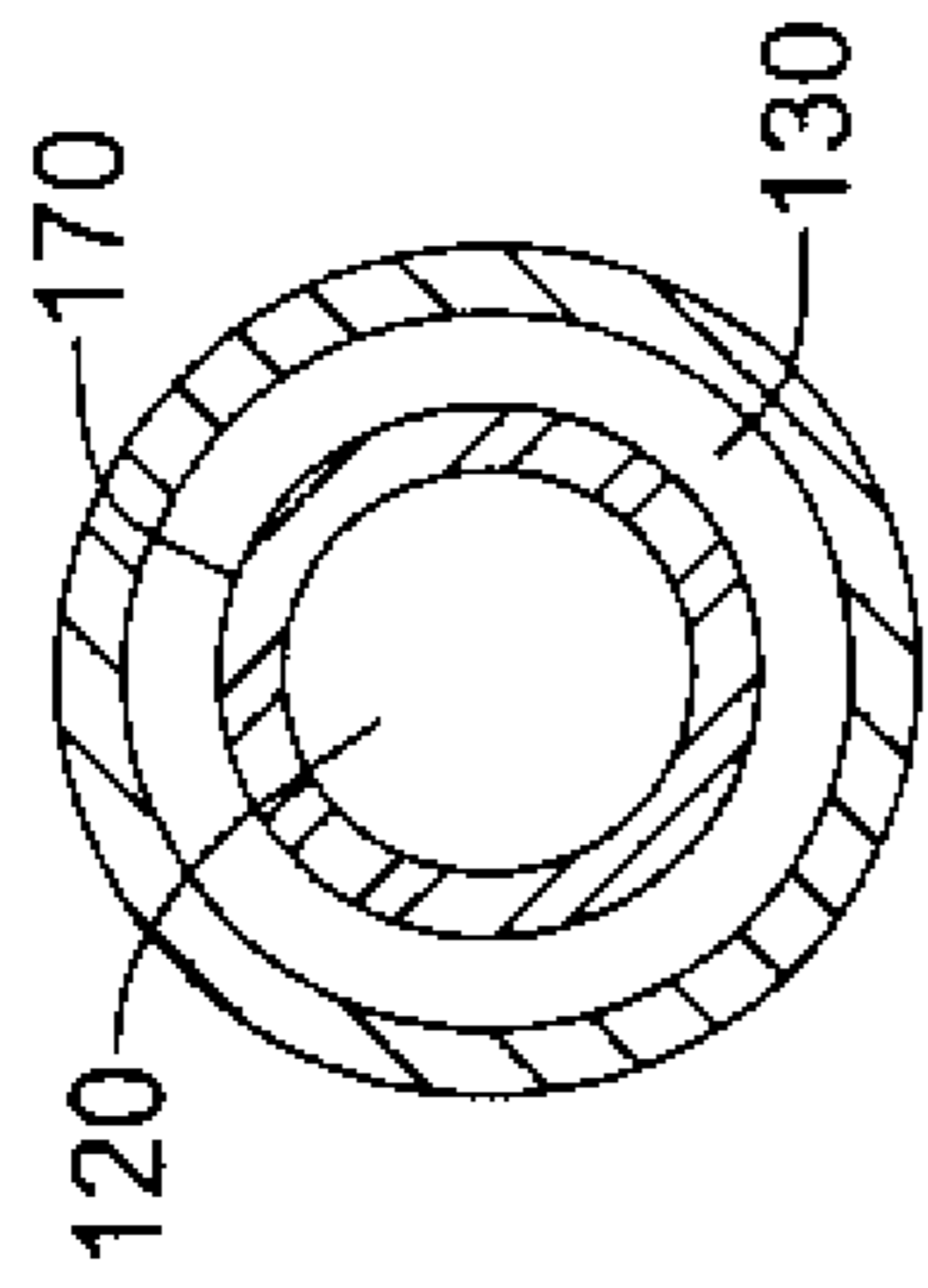


Figure 5

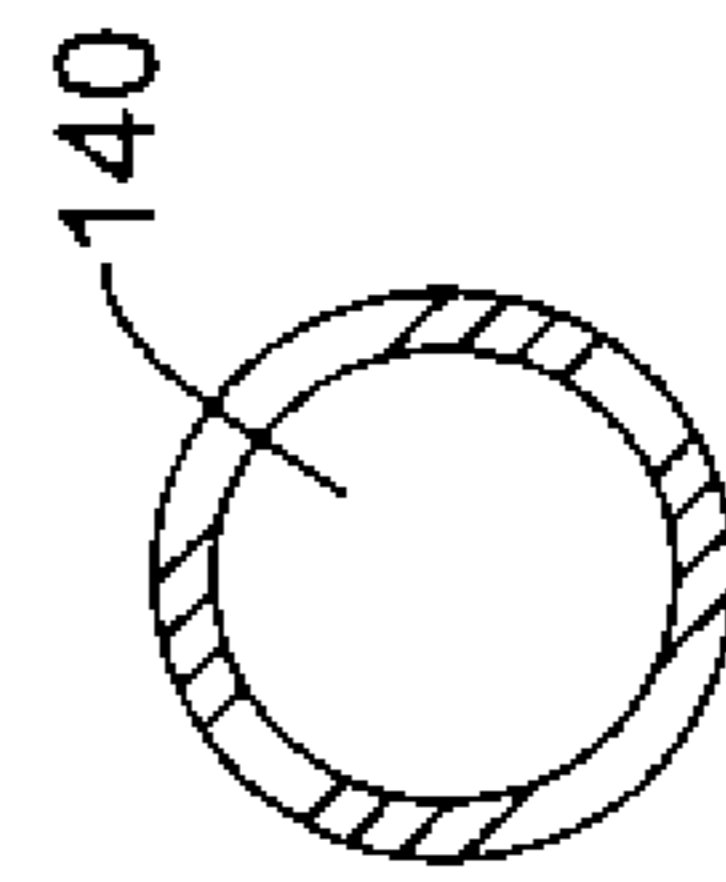


Figure 6

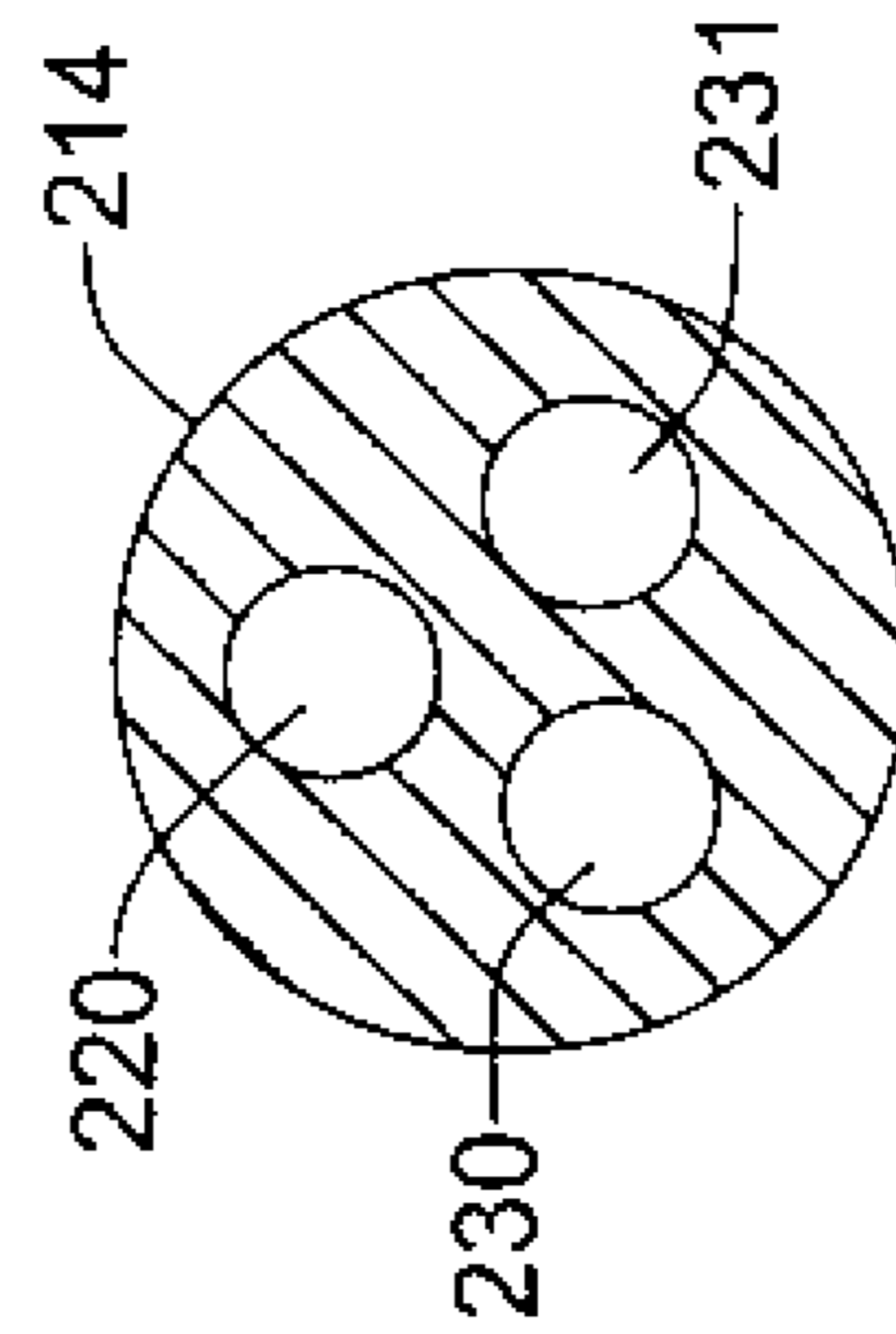


Figure 7

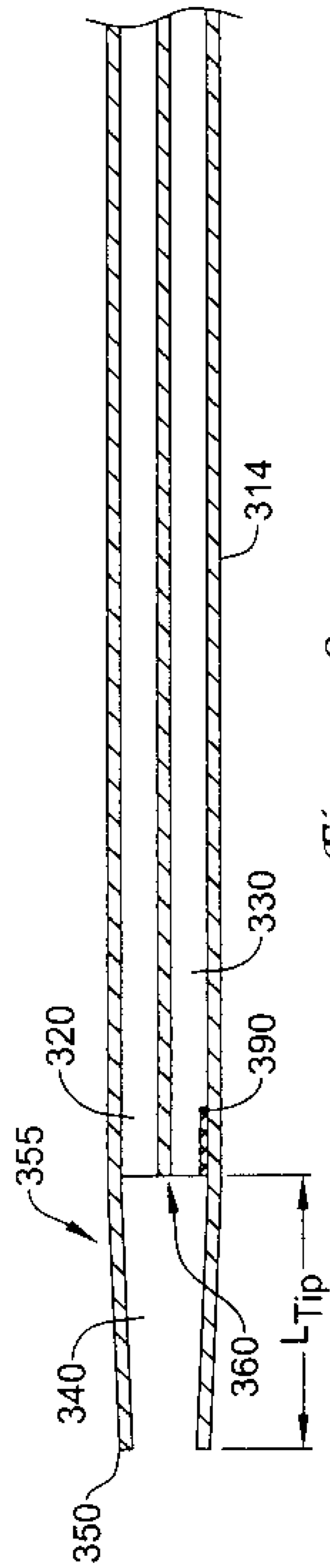


Figure 8

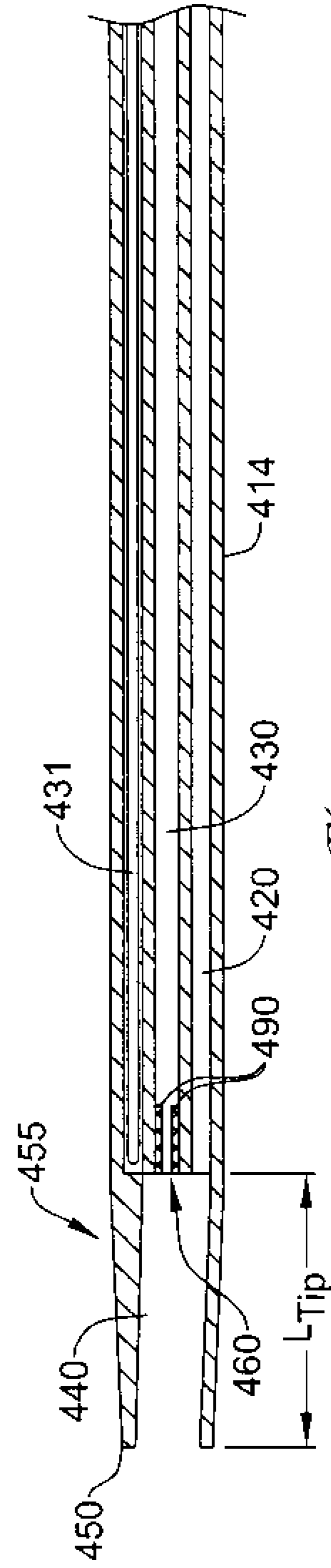


Figure 9

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CATHETER WITH DIRECTED FLOW DESIGN

RELATED APPLICATIONS

This application is a continuation of co-pending U.S. application Ser. No. 10/953,921, filed Sep. 29, 2004, the entire disclosure of which is incorporated herein by reference.

FIELD OF THE INVENTION

The invention relates generally to a catheter useful in performing diagnostic and/or therapeutic modalities in the biliary tree.

BACKGROUND

Endoscopic procedures for treating abnormal pathologies within the alimentary canal system and biliary tree (including the biliary, hepatic and pancreatic ducts) are increasing in number. The endoscope provides access to the general area of a desired duct using direct visualization. However, the duct itself must be navigated using a catheter in conjunction with fluoroscopy and guidewires.

If visualization of the common bile duct is desired, the guidewire can be guided into the common bile duct and the catheter advanced over the guidewire until the distal end thereof is positioned at a desired location for delivery of contrast media for fluoroscopic visualization of the anatomical detail within the common bile duct.

Visualization may reveal selected areas within the common bile duct that require treatment. To treat the selected areas, a different catheter is typically required, necessitating a catheter exchange. A catheter exchange typically involves removing the first catheter from the endoscope, over the guide wire, and advancing a second catheter over the guidewire to the desired treatment site. Once the guidewire is in place relative to the targeted area, it is highly desirable to maintain the position of the guidewire during subsequent catheter procedures, including during a catheter exchange procedure. If the guidewire moves during such a procedure, the guidewire may need to be re-directed through the body ducts to the target site, which is often a difficult and time consuming task.

Single and multi-lumen extrusions are currently used to manufacture catheters. Each lumen is intended to perform a specific function (i.e., injection of contrast media, delivery of guide wire, etc.). The increasing number of lumens has added functionality to catheter design. However, the catheter diameter requirements have remained the same, and this means that the same area has to be broken down into a greater number of smaller sections. This reduction in the size of each lumen has put limits on the performance of each lumen for certain applications.

SUMMARY OF SOME EMBODIMENTS

The invention generally relates to a catheter useful in performing diagnostic and/or therapeutic modalities in the biliary tree. At least some embodiments include a catheter having a first and second lumen merging into a single common lumen near the distal end of the catheter. In some embodiments, the first and the second lumen are side-by-side in a proximal portion of the catheter and coaxial in a distal portion of the catheter. In some embodiments, a restriction is present in a fluid infusion lumen near the distal end of the catheter sufficient to increase a velocity of fluid flowing out of the distal end.

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In one illustrative embodiment, a catheter includes an elongated catheter body having a proximal portion and a distal portion. A first longitudinally accessible lumen and a second lumen extend side-by-side within and along the proximal portion, and the first lumen and the second lumen form a single common lumen within the distal portion which extends to a distal end of the distal portion. The first lumen and second lumen are co-axial within the distal portion prior to forming a single common lumen.

In another illustrative embodiment, a catheter includes an elongated catheter body having a proximal portion and a distal portion. A first lumen having a first cross-sectional area and a second lumen having a second cross-sectional area extend side-by-side within and along the proximal portion. The first lumen and the second lumen form a single common lumen within the distal portion which extends to a distal end of the distal portion. Proximal of the single common lumen, the second lumen comprises a restriction having a third cross-sectional opening area being in a range of about 10 to about 75% of the second cross-sectional area.

In another embodiment, a catheter includes an elongated catheter body having a proximal portion and a distal portion. A first lumen and a second lumen extend side-by-side within and along the proximal portion, and the first lumen and the second lumen form a single common lumen within the distal portion which extends through a tapered distal end of the distal portion. The first lumen and second lumen form a single common lumen within the distal portion, and the first lumen terminates with an open end within the tapered distal end.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention may be more completely understood in consideration of the following detailed description of various embodiments of the invention in connection with the accompanying drawings, in which:

FIG. 1 is a plan view of an illustrative catheter;

FIG. 2 is a longitudinal cross-sectional view of a portion of the illustrative catheter of FIG. 1 taken along line 2-2;

FIGS. 3 to 6 are cross-sectional views of the illustrative catheter of FIGS. 1 and 2 taken along line 3-3 to line 6-6, respectively;

FIG. 7 is a cross-sectional view of another illustrative catheter;

FIG. 8 is a cross-sectional side view of another illustrative catheter of FIG. 1 taken along line 2-2; and

FIG. 9 is a cross-sectional side view of another illustrative catheter of FIG. 1 taken along line 2-2.

DETAILED DESCRIPTION

The following description should be read with reference to the drawings, in which like elements in different drawings are numbered in like fashion. The drawings, which are not necessarily to scale, depict selected embodiments and are not intended to limit the scope of the invention. Although examples of construction, dimensions, and materials may be illustrated for the various elements, those skilled in the art will recognize that many of the examples provided have suitable alternatives that may be utilized.

Unless otherwise indicated, all numbers expressing numerical amounts, quantities of ingredients, and so forth used in the specification and claims are to be understood as being modified in all instances by the term "about". Accordingly, unless indicated to the contrary, the numerical parameters set forth in the foregoing specification and attached claims are approximations that can vary depending upon the

desired properties sought to be obtained by those skilled in the art utilizing the teachings of the present invention. At the very least, and not as an attempt to limit the application of the doctrine of equivalents to the scope of the claims, each numerical parameter should at least be construed in light of the number of reported significant digits and by applying ordinary rounding techniques. Notwithstanding that the numerical ranges and parameters setting forth the broad scope of the invention are approximations, the numerical values set forth in the specific examples are reported as precisely as possible. Any numerical value, however, inherently contains certain errors necessarily resulting from the standard deviations found in their respective testing measurements.

The recitation of numerical ranges by endpoints includes all numbers subsumed within that range (e.g., 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

As used in this specification and the appended claims, the singular forms “a”, “an”, and “the” include plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term “or” is generally employed in its sense including “and/or” unless the content clearly dictates otherwise.

The Figures show exemplary embodiments of a catheter according to the present invention. The catheter can be used in catheter procedures for accessing targeted anatomical regions through, for example, the alimentary canal. In some embodiments, the present invention incorporates features that allow rapid exchange of a catheter by a single operator. The catheter of the present invention can allow shorter length guidewires to be used, resulting in procedures which require less medical personnel, are less time consuming, or less costly. Additionally, the present invention is adaptable to a variety of catheter devices used for catheter procedures within the alimentary canal or any other body lumen.

One illustrative diagnostic technique utilizing a catheter of the present invention is Endoscopic Retrograde Cholangiopancreatography (ERCP). The ERCP technique is an endoscopic technique which involves the placement of a side-viewing instrument within the descending duodenum. The procedure eliminates the need for invasive surgical procedures for identifying biliary stones and other obstructions of the biliary and pancreatic ducts. Utilizing this technique, the Papilla of Vater and common biliary duct are cannulated, contrast medium injected, and the pancreatic ducts and the hepatobiliary tree visualized radiographically or examined with a duodena fiberscope. Skilled medical practitioners can visualize approximately 90-95% of the biliary and pancreatic ducts using this technique. ERCP is typically performed on an X-ray table. During the procedure, the patient's oropharynx is anesthetized with topical lidocaine, and the patient is sedated intravenously with diazepam. Atropine and glucagon are given intravenously to relax the duodenal muscles. To summarize the procedure, an ERCP catheter is initially inserted through the endoscope and into the biliary or pancreatic ducts. A radio-opaque contrast medium is then injected through the lumen of the catheter in order to identify obstructions such as bile stones. Once located and identified, such stones can then be eliminated or destroyed by methods such as mechanical lithotripsy.

The invention generally relates to a catheter useful in performing diagnostic and/or therapeutic modalities in the biliary tree. At least some embodiments include a catheter having a first and a second lumen merging into a single common lumen near the distal end of the catheter. In some embodiments, the first and second lumen are side-by-side in a proximal portion of the catheter and coaxial in a distal portion of the catheter. In some embodiments, a restriction is present in

a fluid infusion lumen near the distal end of the catheter sufficient to increase a velocity of fluid flowing out of the distal end. While the invention is not so limited, an appreciation of various aspects of the invention will be gained through a discussion of the various illustrative embodiments and examples provided below.

Referring to FIG. 1, a plan view of an illustrative catheter **100** is shown. The catheter **100** includes an illustrative hub **102** connected to a proximal end **111** of an elongated catheter body **110**. The hub **102** can include a guidewire introducer **104**. The elongated catheter body **110** includes a proximal portion **112** and a distal portion **114**. The proximal portion **112** can have a first cross-sectional diameter, and the distal portion **114** can have a second cross-sectional diameter that can be smaller than the first cross-sectional diameter. The elongated catheter body **110** can include two or more lumens extending along at least a portion of the elongated catheter body **110** length L_{total} . The elongated catheter body **110** length L_{total} can extend from the proximal end **111** to a catheter distal end **150**. In illustrative embodiments, the elongated catheter body **110** length L_{total} can be in a range of about 100 to about 300 cm, or about 150 to about 250 cm, or about 175 to about 225 cm, or about 200 cm.

Elongate catheter body **110** may be sized for slidable passage through the lumen of an endoscope (not shown). Elongate catheter body **110** can be formed by an extrusion process. Elongate catheter body **110** may be formed of an extruded polymeric material. In one embodiment, the polymeric material can be polytetrafluoroethylene, polyether block amide, nylon or a combination or blend of these. Elongate catheter body **110** can have a varying flexibility along its length. For example, the proximal portion **112** can be less flexible than the distal portion. The flexibility can be varied by selection of material along the elongate catheter body **110** length and/or by adding to reducing any layers forming the elongate catheter body **110**. Catheters which are contemplated include, but are not limited to, cannulas, sphincterotomes, cytology devices, and devices for stone retrieval and stent placement.

In some embodiments, the elongated catheter body **110** can include a first lumen **120** which is laterally accessible to allow the catheter **100** to operate as a rapid exchange or single operator exchange catheter. The term “laterally accessible lumen” is defined herein to refer to a lumen that can be accessed along its length and includes lumens that have a C-shaped profile, a U-shaped, a closed lumen having a longitudinal area of perforations or weakness to allow a user to longitudinally open the lumen, and the like. FIG. 3 is a cross-sectional view of the catheter **100** taken along line 3-3. This Figure shows an illustrative side-by-side two lumen construction where the first lumen **120** has an open channel **122** (C-shaped) that allows a guidewire to move laterally from the first lumen **120** to a position exterior of the first lumen **120**. Referring back to FIG. 1, at least a portion of the first lumen **120** is closed forming an exchange length L_{ex} that extends from a distal guidewire port **124** to the distal end **150**. In illustrative embodiments, the exchange length L_{ex} can be in a range of about 1 to about 30 cm, or about 2 to about 10 cm, or about 3 to about 8 cm, or about 4 to about 6 cm.

In some embodiments, the elongate catheter body **110** includes a distal taper **155** which tapers to distal end **150**. Additionally, the distal portion **114** can include high contrast, or color coded distal markers **151**. At least portions of the distal portion **114** can be radiopaque for fluoroscopic visualization of the distal taper **155** region during a catheter procedure.

FIG. 2 is a longitudinal cross-sectional view of a portion of the illustrative catheter **100** taken along line 2-2. This Figure

shows the distal portion **114** of the elongated catheter body **110**. In this illustrative embodiment, at least a first lumen **120** and a second lumen **130** extend side-by-side within the proximal portion **112** and a portion of the distal portion **114** of the elongated catheter body **110**. The first lumen **120** and the second lumen **130** merge near the distal end **150** forming a common distal lumen **140** within a portion of the distal portion **114**. The common distal lumen **140** extends to the distal end **150** of the distal portion **114**. In one illustrative embodiment, the distal portion **114** includes a tapered distal tip **155** having a tip length L_{tip} that extends from a point where the tip begins to reduce in diameter to the distal end **150**. The tip length L_{tip} can be in a range of about 0.1 to about 5%, or about 0.2 to about 1%, or about 0.2 to about 0.75% of the elongated catheter body **110** length L_{total} . In an illustrative embodiment, the tip length L_{tip} can be in a range of about 1 to about 30 cm, or about 2 to about 10 cm, or about 3 to about 8 cm, or about 5 cm. In another illustrative embodiment, the tip length L_{tip} can be in a range of about 1 to about 30 cm, or about 5 to about 20 cm, or about 10 to about 15 cm, or about 13 cm.

Formation of the single common lumen **140** can be accomplished in a variety of ways. In an illustrative embodiment, single common lumen **140** begins as a lumen transition **180** where the second lumen **130** forms around the first lumen **120**. This illustrative embodiment is shown in FIG. 4 which is taken along the line 4-4 of FIG. 2. FIG. 5 is taken along line 5-5 of FIG. 2. FIG. 5 shows the first lumen **120** within the second lumen **130** in a co-axial arrangement within the distal portion **114** of the elongated catheter body **110**. In some embodiments, the first lumen **120** ends or terminates as an open end **160** proximal of the distal end **150**. The first lumen **120** can end or terminate as an open end **160** within the tapered distal tip **155**. The first lumen **120** can be in fluid communication with the second lumen **130** and the single common lumen **140** at the first lumen open end **160**. The single common lumen **140** can begin at the first lumen open end **160**. FIG. 6 is taken along line 6-6 of FIG. 2. FIG. 6 shows a single common lumen **140**. In an illustrative embodiment, the single common lumen **140** distal end **150** can have an inside cross-sectional diameter in the range of about 0.75 to about 1.25 mm or about 1 mm. In illustrative embodiments, the first lumen open end **160** is less than about 20, 15, 10, 5, 4, 3, 2 or 1 mm from the distal end **150**. In other illustrative embodiments, the first lumen open end **160** can be about 1 to about 15 mm, or about 1 to about 10 mm, or about 1 to about 5 mm, or about 5 to about 10 mm from the distal end **150**.

The first lumen **120** can have a first cross-sectional area. The second lumen **130** can have a second cross-sectional area. In at least some embodiments, the second lumen **130** can have a restriction **190** that reduces the second lumen **130** second cross-sectional area. This restriction **190** can provide an opening having a third cross-sectional area that is less than the second cross-sectional area. If fluid is provided through the second lumen **130** at a constant pressure, the restriction **190** can increase the velocity of the fluid through the restriction **190** opening. This increased fluid velocity into the single common lumen **140** near the distal end **150** aids in minimizing fluid flow back into the first lumen **120**. In illustrative embodiments the restriction **190** opening third cross-sectional area can be in a range of about 10 to about 75%, or about 25 to about 50% of the second lumen **130** second cross-sectional area proximal the restriction. In some embodiments, the single common lumen **140** can have a fourth cross-sectional area that is greater than the second lumen **130** second cross-sectional area.

The first lumen **120** can include a tube **170** that extends across the lumen transition **180**. This tube **170** can be formed

of any material and can be integral with the first lumen **120** proximal of the lumen transition **180**. The tube **170** can also be thin-walled and inserted within lumen **120** and affixed thereto. In one embodiment, the tube **170** is formed of a polyimide material, is sized to accept a guide wire, and can be about 5 to about 30 cm in length. The tube **170** can be fixed to the first lumen **120** with an adhesive, for example. The tube **170** can be rigid enough such that the tube does not collapse when injection fluid applies pressure around the tube **170** during operation.

The first lumen **120** can be a guidewire lumen. In an illustrative embodiment, the guidewire lumen **120** extends longitudinally between proximal portion **112** and distal end **150** of the elongate catheter body **110**. Further, guidewire lumen **120** is sized to receive a guide wire. Guidewire lumen **120** may be a tubular member which is extruded integral with the elongate catheter body **110**, or alternatively, the guidewire lumen **120** may be a separate tubular member which is coupled to elongate catheter body **110**. It is recognized that guidewire lumen **120** may be formed anywhere along the elongate catheter body **110**, may be an extension of the elongate catheter body **110** coupled to distal end **150**, or guidewire lumen **120** may run the entire length of the elongate catheter body **110**.

The second lumen **130** can be an ancillary lumen. The ancillary lumen **130** can be an injection lumen, allowing for high contrast media flow capability for bubble-free opacification and for excellent visualization of a desired anatomical region. Additionally or alternatively, ancillary lumen **130** may be used for or as part of other ancillary devices, such as a cutting wire lumen or a retrieval balloon lumen.

FIG. 7 is a cross-sectional view of another illustration catheter embodiment. In this embodiment, three lumens **220**, **230**, **231** extend side-by-side along at least a portion of the distal portion **214**. A guidewire lumen **220**, an injection lumen **230**, and an ancillary lumen **231** are shown. The ancillary lumen **231** may be used for or as part of another ancillary device, such as a cutting wire lumen, or a balloon inflation lumen, as desired.

FIG. 8 is a cross-sectional side view of another illustrative catheter embodiment taken along line 2-2 of FIG. 2. This Figure shows the distal portion **314** of the elongated catheter body. In this illustrative embodiment, at least a first lumen **320** and a second lumen **330** extend side-by-side within the proximal portion and distal portion **314** of the elongated catheter body. The first lumen **320** and the second lumen **330** merge near the distal end **350** forming a common distal lumen **340** within the distal portion **314**. The common distal lumen **340** extends to the distal end **350** of the distal portion **314**. In one illustrative embodiment, the distal portion **314** includes a tapered distal tip **355** having a tip length L_{tip} that extends from a point where the tip begins to reduce in diameter to the distal end **350**. The tip length L_{tip} can be in a range of about 0.1 to about 5%, or about 0.2 to about 1%, or about 0.2 to about 0.75% of the elongated catheter body length L_{total} . In an illustrative embodiment, the tip length L_{tip} can be in a range of about 1 to about 30 cm, or about 2 to about 10 cm, or about 3 to about 8 cm, or about 5 cm. In another illustrative embodiment, the tip length L_{tip} can be in a range of about 1 to about 30 cm, or about 5 to about 20 cm, or about 10 to about 15 cm, or about 13 cm.

Formation of the single common lumen **340** can be accomplished in a variety of ways. In the illustrative embodiment, a single common lumen **340** begins as both lumens **320**, **330** terminate with open ends. In this embodiment, the first lumen **320** and the second lumen **330** end or terminate as open ends **360** proximal of the distal end **350**. The first lumen **320** can end or terminate as an open end **360** within the tapered distal

tip **355**. The second lumen **330** can end or terminate as an open end **360** within the tapered distal tip **355**. In illustrative embodiments, the first lumen **320** and the second lumen **330** terminate at about the same location merging into a single common lumen **340**. In other illustrative embodiments, the first lumen **320** and the second lumen **330** can terminate at different locations, then the lumen open end **360** closest to the distal end **350** merges into a single common lumen **340**. The first lumen **320** can be in fluid communication with the second lumen **330** and the single common lumen **340** at the lumen open end **360**. In an illustrative embodiment, the single common lumen **340** distal end **350** can have an inside diameter in the range of about 0.75 to about 1.25 mm, or about 1 mm. In illustrative embodiments, the first lumen or second lumen open end **360** can be not more than about 20, 15, 10, 5, 4, 3, 2 or 1 mm from the distal end **350**. In other illustrative embodiments, the first lumen or second lumen open end **360** can be about 1 to about 15 mm, or about 1 to about 10 mm, or about 1 to about 5 mm, or about 5 to about 10 mm from the distal end **350**.

The first lumen **320** can have a first cross-sectional area. The second lumen **330** can have a second cross-sectional area. In at least some embodiments, the second lumen **330** can have a restriction **390** that reduces the second lumen **330** second cross-sectional area. This restriction **390** can provide an opening having a third cross-sectional area that is less than the second cross-sectional area. If fluid is provided through the second lumen **330** at a constant pressure, the restriction **390** can increase the velocity of the fluid through the restriction **390** opening. This increased fluid velocity into the single common lumen **340** near the distal end **350** aids in minimizing fluid flow back into the first lumen **320**. In illustrative embodiments the restriction **390** opening third cross-sectional area can be in a range of about 10 to about 75%, or about 25 to about 50% of the second lumen **330** second cross-sectional area proximal the restriction. In some embodiments, the single common lumen **340** can have a fourth cross-sectional area that is greater than the second lumen **330** second cross-sectional area.

FIG. 9 is a cross-sectional side view of another illustrative catheter embodiment taken along line 2-2 of FIG. 1. This Figure shows the distal portion **414** of the elongated catheter body. In this illustrative embodiment, at least a first lumen **420**, a second lumen **430**, and a third lumen **431** extend side-by-side within the proximal portion and distal portion **414** of the elongated catheter body. The third lumen **431** can be an ancillary lumen **431**. The ancillary lumen **431** can be used for or as part of other ancillary devices, such as a cutting wire lumen, a balloon inflation lumen, or a retrieval balloon lumen. It is understood that the catheters described herein can include more or less lumens, as desired. An illustrative sphincterotome device utilizing a cutting wire lumen is disclosed in U.S. Pat. No. 6,579,300, incorporated by reference herein.

The first lumen **420** and the second lumen **430** merge near the distal end **450** forming a common distal lumen **440** within the distal portion **414**. The common distal lumen **440** extends to the distal end **450** of the distal portion **414**. In one illustrative embodiment, the distal portion **414** includes a tapered distal tip **455** having a tip length L_{tip} that extends from a point where the tip begins to reduce in diameter to the distal end **450**. The tip length L_{tip} can be in a range of about 0.1 to about 5%, or about 0.2 to about 1%, or about 0.2 to about 0.75% of the elongated catheter body length L_{total} . In an illustrative embodiment, the tip length L_{tip} can be in a range of about 1 to about 30 cm, or about 2 to about 10 cm, or about 3 to about 8 cm, or about 5 cm. In another illustrative embodiment, the tip

length L_{tip} can be in a range of about 1 to about 30 cm, or about 5 to about 20 cm, or about 10 to about 15 cm, or about 13 cm.

Formation of the single common lumen **440** can be accomplished in a variety of ways. In the illustrative embodiment, a single common lumen **440** begins as both lumens **420**, **430** terminate with open ends **460**. In this embodiment, the first lumen **420** and the second lumen **430** end or terminate as open ends **460** proximal of the distal end **450**. The first lumen **420** can end or terminate as an open end **460** within the tapered distal tip **455**. The second lumen **430** can end or terminate as an open end **460** within the tapered distal tip **455**. In illustrative embodiments, the first lumen **420** and the second lumen **430** terminate at about the same location merging into a single common lumen **440**. In other illustrative embodiments, the first lumen **420** and the second lumen **430** can terminate at different locations, then the lumen open end **460** closest to the distal end **450** merges into a single common lumen **440**. The first lumen **420** can be in fluid communication with the second lumen **430** and the single common lumen **440** at the lumen open end **460**. In an illustrative embodiment, the single common lumen **440** distal end **450** can have an inside diameter in the range of about 0.75 to about 1.25 mm or about 1 mm. In illustrative embodiments, the first lumen or second lumen open end **460** can be not more than about 20, 15, 10, 5, 4, 3, 2 or 1 mm from the distal end **450**. In other illustrative embodiments, the first lumen or second lumen open end **460** can be about 1 to about 15 mm, or about 1 to about 10 mm, or about 1 to about 5 mm, or about 5 to about 10 mm from the distal end **450**.

The first lumen **420** can have a first cross-sectional area. The second lumen **430** can have a second cross-sectional area. In at least some embodiments, the second lumen **430** can have a restriction **490** that reduces the second lumen **430** second cross-sectional area. This restriction **490** can provide an opening having a third cross-sectional area that is less than the second cross-sectional area. If fluid is provided through the second lumen **430** at a constant pressure, the restriction **490** can increase the velocity of the fluid through the restriction **490** opening. This increased fluid velocity into the single common lumen **440** near the distal end **450** aids in minimizing fluid flow back into the first lumen **420**. In illustrative embodiments the restriction **490** opening third cross-sectional area can be in a range of about 10 to about 75%, or about 25 to about 50% of the second lumen **430** second cross-sectional area proximal the restriction. In some embodiments, the single common lumen **440** can have a fourth cross-sectional area that is greater than the second lumen **430** second cross-sectional area.

The present invention should not be considered limited to the particular examples described above, but rather should be understood to cover all aspects of the invention as fairly set out in the attached claims. Various modifications, equivalent processes, as well as numerous structures to which the present invention can be applicable will be readily apparent to those of skill in the art to which the present invention is directed upon review of the instant specification.

What is claimed is:

1. A medical device comprising:

an elongate tubular member having a proximal portion with a proximal end and having a distal portion with a distal end, the elongate tubular member including a first lumen extending distally from the proximal end and a second lumen extending distally from the proximal end and disposed side-by-side with the first lumen along the proximal portion, the first lumen being laterally accessible along at least a portion of the length thereof; and

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a second tubular member disposed within at least a portion of the first lumen, the second tubular member having a curved distal region;

wherein the first lumen and second lumen form a single common lumen having an open distal end within the distal portion of the elongate tubular member.

2. The medical device of claim 1, wherein a proximal end of the second lumen has a first cross-sectional area and a distal end of the second lumen has a second cross-sectional area.

3. The medical device of claim 2, wherein the second cross-sectional area is smaller than the first cross-sectional area.

4. The catheter according to claim 3, wherein the second cross-sectional area is in a range of about 10 to about 75% of the first cross-sectional area.

5. The catheter according to claim 3, wherein the second cross-sectional area is in a range of about 25 to about 50% of the first cross-sectional area.

6. The medical device of claim 2, wherein the single common lumen has a third cross-sectional area that is greater than the first cross-sectional area.

7. The medical device of claim 1, wherein the second tubular member forms a distal portion of the first lumen.

8. The medical device of claim 7, wherein the second lumen surrounds the second tubular member proximal to the single common lumen.

9. The medical device of claim 1, wherein the second lumen comprises a restriction.

10. A medical device comprising:

an elongated tubular body having a proximal portion with a proximal end and having a distal portion with a distal end;

a first lumen extending distally from the proximal end of the tubular body, the first lumen having a proximal portion and a distal portion, the proximal portion of the first lumen having a laterally accessible region and the distal portion of the first lumen having a closed region;

a second lumen extending distally from the proximal end of the tubular body, the second lumen having a proximal portion and distal portion, the first and second lumens extending within and along the proximal portion of the elongated catheter body;

a hub assembly adjacent to the proximal portion of the tubular body;

wherein the second lumen is defined along an inner wall surface of the tubular body; and

a restriction disposed within the distal portion of the second lumen and attached to the inner wall surface;

wherein the first lumen and the second lumen form a single common lumen having an open distal end within the

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distal portion of the tubular body which extends to and through a distal end of the distal portion of the tubular body.

11. The medical device of 10, wherein the proximal portion of the second lumen has a first cross-sectional area and the distal portion of the second lumen at the restriction has a second cross-sectional area.

12. The medical device of claim 11, wherein the second cross-sectional area is smaller than the first cross-sectional area.

13. The medical device of claim 10, wherein the second lumen surrounds first lumen along a length prior to forming the single common lumen.

14. The medical device claim 10, wherein the elongated tubular body comprises a third lumen.

15. The medical device of claim 10, wherein the proximal portion of the tubular body has a first diameter and the distal portion of the tubular body has a second diameter that is smaller than the first diameter.

16. A medical device comprising:

an elongate tubular member having a proximal portion and a distal portion, the elongate tubular member including a first lumen extending distally from the proximal portion and a second lumen extending side-by-side with the first lumen along the proximal portion;

a second tubular member disposed within at least a portion of the first lumen;

a hub assembly adjacent to the proximal portion of the first tubular member; and

a restriction disposed within a distal portion of the second lumen

wherein the first lumen and second lumen form a single common lumen having an open distal end within the distal portion of the elongate tubular member;

wherein a distal region of the second tubular member extends distally from the first lumen and into the single common lumen;

wherein at least a portion of the distal region of the second tubular member and the single common lumen are coaxial; and

wherein the first lumen has a laterally accessible region.

17. The medical device of 16, wherein a proximal portion of the second lumen has a first cross-sectional area and the distal portion of the second lumen at the restriction has a second cross-sectional area.

18. The medical device of claim 17, wherein the second cross-sectional area is smaller than the first cross-sectional area.

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